

§ 108.6

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a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and Drug Administration's witnesses and to present witnesses on his own behalf.

(c) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether a permit is required and shall so inform the manufacturer, processor, or packer in writing, with the reasons for his decision.

(d) The Commissioner's determination of the need for a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

[42 FR 14334, Mar. 15, 1977, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

§ 108.6 Revocation of determination of need for permit.

(a) A permit shall be required only during such temporary period as is necessary to protect the public health.

(b) Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions established in subpart B of this part and is likely to remain in compliance, he shall, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant shall, upon request, be afforded a hearing conducted in accordance with § 108.5 (b) and (c) as soon as practicable. Such revocation is without prejudice to the initiation of further permit proceedings with respect to the same manufacturer, processor, or packer should later information again show the need for a permit.

§ 108.7 Issuance or denial of permit.

(a) After a determination and notification by the Commissioner in accordance with the provisions of § 108.5 that a manufacturer, processor, or packer requires a permit, such manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by him unless he holds a permit issued by the Commissioner or obtains advance written approval of the Food and Drug Administration pursuant to § 108.12(a).

(b) Any manufacturer, processor, or packer for whom the Commissioner has made a determination that a permit is necessary may apply to the Commissioner for the issuance of such a permit. The application shall contain such data and information as is necessary to show that all mandatory requirements and conditions for the manufacturer, processing or packing of a food for which regulations are established in subpart B of this part are met and, in particular, shall show that the deviations specified in the Commissioner's determination of the need for a permit have been corrected or suitable interim measures established. Within 10 working days after receipt of such application, (except that the Commissioner may extend such time an additional 10 working days where necessary), the Commissioner shall issue a permit, deny the permit, or offer the applicant a hearing conducted in accordance with § 108.5 (b) and (c) as to whether the permit should be issued. The Commissioner shall issue such a permit to which shall be attached, in addition to the mandatory requirements and conditions of subpart B of this part, any additional requirements or conditions which may be necessary to protect the public health if he finds that all mandatory requirements and conditions of subpart B of this part are met or suitable interim measures are established.

(c) Denial of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.